

Appl. No. 10/792,076  
Amdt. AF dated August 4, 2006  
Reply to Final Office Action of June 5, 2006

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### REMARKS

Applicants have carefully reviewed the Final Office Action mailed June 5, 2006, prior to preparing this response. Currently claims 1-5, 7-28, 30, 32-35 and 37-44 are pending in the application, wherein claims 1-4, 8-11, 17-19, 27, 28, 34 and 35 have been rejected, claims 5, 12-16, 20-27, 30, 36 and 40-44 have been withdrawn from consideration consequent an Examiner induced requirement for restriction, and claims 7, 32-33 and 38-39 are objected to as being dependent upon a rejected base claim but otherwise indicated as allowable. Favorable consideration of the following remarks is respectfully requested.

Claims 7, 32-33 and 38-39 stand objected to as being dependent upon a rejected base claim, but otherwise indicated as allowable. In view of this indication, claims 7, 32-33 and 38-39 have been amended into independent form including all limitations of their respective rejected base claims in an effort to expedite prosecution of these claims. Thus, the amendments of claims 7, 32-33 and 38-39 do not raise new issues that would require further consideration and/or search. In making the amendments to claims 7, 32-33 and 38-39, Applicants do not concede the appropriateness of rejections made in the Final Office Action. Favorable consideration of claims 7, 32-33 and 38-39 in the form of a Notice of Allowance is respectfully anticipated.

Claims 1-4, 6, 8-9, 17, 28-29, 31 and 34-35 stand rejected under 35 U.S.C. §102(b) as being anticipated by Roberts et al., U.S. Patent No. 5,545,209. Applicants respectfully traverse this rejection. Specifically, Applicants respectfully disagree with two assertions made by the Examiner in the Office Action. First, the Examiner erroneously states, "The balloon proximal portion is *releasably attached* to the shaft by epoxy adhesive." (Emphasis added.) Second, the Examiner further erroneously states, "The term 'releasably' or 'releasable' is considered to be intended use." Each of these statements is erroneous for at least the reasons presented in a previous response and currently maintained.

As for the first erroneous proposition, the proximal portion of the balloon taught in Roberts et al. is not releasably attached to the shaft. "Releasably attached," as uniformly used in the current application is intended to describe a particular type of attachment between two components. Namely, as used in the present application, "releasably attached," describes the relationship of two components which are attached to one another in a first operational state, yet may be unattached from one another in another operational state. Thus, components which are

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releasably attached to one another are distinguishable from components which are permanently attached to one another (e.g., not separable under ordinary operating conditions without damaging, and/or causing unintended consequences to the components). Indeed, one of skill in the art would conclude that the balloon taught in Roberts et al. is permanently attached to the shaft, and an instance in which the balloon was separated from the shaft would signify a potentially injurious failure mode of the device not intended during normal operation of the device. In fact, one of skill in the art would likely conclude that the balloon of a balloon catheter taught in Roberts et al. will rupture at excessive pressure levels, while the bond formed between the balloon and the shaft by the epoxy adhesive remains unaffected. Thus, the balloon would fail prior to severance of the bond between the balloon and the shaft. To suggest the balloon taught in Roberts et al. is releasably attached to the shaft would be contrary to the teachings of Roberts et al. and contrary to the general understanding of balloon catheter construction to one skilled in the art.

As for the second erroneous proposition, the term "releasably attached" is a structural limitation of the claim which must be given patentable weight. Applicants assert the prior art must teach the claimed invention in as much detail, including all structural limitations, as provided in the claim. See *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ2d 1913 (Fed. Cir. 1989); *Lindemann Maschinenfabrik v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984). Thus, the part-to-part relationship of components must be considered when evaluating claims. See *Lindemann Maschinenfabrik v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984).

As currently claimed, the term "attached", which identifies the relationship of the claimed portion of the balloon with the shaft, is modified by the term "releasably". Thus the limitation "releasably attached", as distinguished from being permanently attached or otherwise attached, describes the part-to-part relationship between the claimed portion of the balloon with the shaft. Thus, the disputed claim limitation serves to unambiguously define present structural attributes of interrelated components of the claimed invention, and does not merely recite an intended use of the claimed invention as opined by the Examiner. As such, the claim limitation should be given patentable weight.

An illustrative example which may be useful in understanding Applicants' position may be the relationship between a self-adhesive stamp (a stamp which employs a pressure sensitive

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adhesive), the backing paper on which the stamp is provided, and an envelope. The stamp, due to the low affinity between the adhesive on the stamp and the wax surface of the backing paper, is releasably attached to the backing paper. Whereas, once the stamp is secured to the envelope, the stamp may be considered permanently attached to the envelope. During normal use, the stamp may not be removed from the envelope without damaging the stamp and/or the envelope. The fact that the stamp is releasably attached to the backing paper describes the relationship between the stamp and the backing paper and provides no inkling to the intended use of the stamp. Similarly, the fact that the stamp is permanently attached to the envelope describes the relationship between the stamp and the envelope.

In view of this example, the disputed term "releasably attached" indeed describes the part-to-part relationship between two components of the claimed invention, and as such must be given patentable weight.

Even if the claim limitation were construed as functional in nature, the limitation should not be disregarded as a mere recitation of intended use. The Manual of Patent Examining Procedure, which the Examiner has an obligation to follow, states "[a] functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used." M.P.E.P. §2173.05(g). This section of the M.P.E.P., which gives guidance for Functional Limitations, continues by providing an example of when the court noted that the claim term "operatively connected" is "a general descriptive claim term frequently used in patent drafting to reflect a functional relationship between claimed components." M.P.E.P. §2173.05(g), citing *Innova/Pure Water Inc. v. Safari Water Filtration Sys. Inc.*, 381 F.3d 1111, 1117-20, 72 USPQ2d 1001, 1006-08. As such, the court stated the term "operatively connected" must be construed to be given its ordinary meaning. Following a similar rationale, if the currently disputed claim limitation were construed as functional in nature, it should be given patentable weight in describing the relationship between claimed components of the invention. Thus, the disputed term should be construed in light of the specification and not disregarded as a mere recitation of intended use.

At least because the term "releasably attached" is due appropriate patentable weight and because Roberts et al. do not disclose a catheter wherein the balloon is releasably attached to the

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catheter shaft, Applicants submit that Roberts et al. fail to anticipate the rejected claims. Withdrawal of the rejection is respectfully requested.

Claims 1-4, 6, 9, 28-29, 34, 35 and 37 stand rejected under 35 U.S.C. §102(b) as being anticipated by Briscoe et al., U.S. Patent No. 6,458,096. Applicants respectfully traverse this rejection.

Briscoe et al. disclose a balloon catheter having an auto-regulating structure to prevent overinflation of the balloon. The auto-regulating structure is a tight-fitting distal end that discharges more fluid as the balloon is inflated. Briscoe et al. describe the proximal end of the balloon as being "secured to the outside surface of the catheter 14 by an adhesive or other conventional means." Briscoe et al. at column 5, lines 20-23. One of ordinary skill in the art would understand this as indicating the proximal end of the balloon is permanently attached to the shaft. Logically, the conventional means used to secure the balloon of Briscoe at the proximal end is not, as the discussion above with regard to Roberts et al., a releasable attachment. Furthermore, the distal end of the balloon taught in Briscoe et al. "is not secured to the outside surface of the catheter 14." Briscoe et al. at column 5, lines 23-24. Instead, the distal end of the balloon "tightly surrounds the catheter." Briscoe et al. at column 5, lines 25-26. The distal end of the balloon remains unattached to the shaft such that when the balloon is pressurized, the distal end of the balloon will extend longitudinally along the shaft. See Briscoe et al. at column 5, line 53 through column 6, line 40. At elevated pressures or flow rates, "the distal end 50 of the balloon 46 will expand radially outwardly from the catheter 14 thereby creating a fluid flow path around substantially the entire periphery of the catheter 14." Thus, it is clear from the teachings of Briscoe et al. that the distal end of the disclosed balloon is not attached to the shaft. Furthermore, the proximal end of the disclosed balloon is secured to the balloon in a conventional fashion.

At no place throughout Briscoe et al. is a portion of the balloon disclosed as being releasably attached to the shaft as currently claimed. For at least these reasons, Applicants submit that claims 1, 28 and 34 are not anticipated by Briscoe et al. Claims 2-4, 9 and 35, which depend from one of claims 1, 28 and 34 and contain significant additional elements, are also believed patentable over Briscoe et al. Withdrawal of the rejection of these claims is respectfully requested.

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Claims 10-11 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Roberts et al., U.S. Patent No. 5,545,209, in view of Stevens, U.S. Patent No. 4,798,586. Applicants respectfully traverse this rejection, asserting a *prima facie* case of obviousness has not been established.

For at least the reasons stated above Roberts et al. fail to anticipate claim 1, of which claims 10-11 depend from. Stevens fails to remedy the shortcomings of Roberts et al. For at least this reason, a *prima facie* case of obviousness has not been established with the cited combination and withdrawal of the rejection is respectfully requested.

Claims 18-19 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Roberts et al., U.S. Patent No. 5,545,209, in view of Sugiyama et al., U.S. Patent No. 4,964,853. Applicants respectfully traverse this rejection, asserting a *prima facie* case of obviousness has not been established.

For at least the reasons stated above Roberts et al. fail to anticipate claim 1, of which claims 18-19 depend from. Sugiyama et al. fail to remedy the shortcomings of Roberts et al. For at least this reason, a *prima facie* case of obviousness has not been established with the cited combination and withdrawal of the rejection is respectfully requested.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Elaine Lim et al.

By their Attorney,

Date: 8/4/06



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